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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/238,080	05/03/94	COLLINS M	2583511

18M2/0620

NORVAL B. GALLOLWAY
AMOCO CORP.
AMOCO TECH. LAW DEPT.
3100 WOODCREEK DRIVE
DOWNERS GROVE, IL 60515

EXAMINER	
REES D.	

ART UNIT	PAPER NUMBER
1807	10

DATE MAILED: 06/20/96

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/238,080	COLLINS ET AL.
Examiner	**Group Art Unit**
Dianne Rees	1807

☒ Responsive to communication(s) filed on *12/5/95,3/7/96*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *25-50* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *25-50* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part III DETAILED ACTION

Applicant's election without traverse of Group I in Paper No. 8 is acknowledged.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to all earlier filed application(s) in the first sentence of the specification (37 CFR 1.78).

Claim Rejections - 35 USC § 112

1. Claims 43 and 44 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 is indefinite in the recitation in step (d) of " contacting the amplified target polynucleotide with a second support which binds to the target polynucleotide and detecting the presence of the amplified target polynucleotide" in that it

is unclear if the second support actually "binds" to the polynucleotide or only does so indirectly through a labeled probe. It is further unclear if the labelled probe is bound to the second support. Clarification is requested.

In claim 44, step (c) is indefinite in the recitation of "to a solid medium include a second support" as the claim seems to be missing word(s). Clarification is requested.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103,

the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 25-42,44,and 48-50 are rejected under 35 U.S.C. § 103 as being unpatentable over Vary et al. (USPAT 4851331,, filed May 16, 1986) in view of Henson et al. (ORTHO DIAGNOSTICS, EP 0 139 489, published 2/5/85).

Vary et al. teaches a method for amplifying and detecting a target polynucleotide in a sample comprising amplifying a target polynucleotide, immobilizing said amplified polynucleotide on a support, separating the amplified polynucleotide on the support from the sample and detecting the amplified polynucleotides. Vary teaches the advantage of solid supports in "capturing a probe specifically and in high concentration with major other material not contributing to nonspecific signal" (column 4). The method of Vary differs from that of the claimed invention in that Vary does not bind a target polynucleotide to a support or separate the target from the sample prior to amplification. Vary also does not explicitly teach retrieveable supports.

However Henson et al. teaches a nucleic acid detection method in which an enzyme labeled nucleic acid probe is

hybridized to a sequence of interest as well as a biotinylated nucleic acid probe which may immobilized on an avidin coated microparticle (i.e a retrieveable solid support) (see abstract). Following separation of the support and bound target polynucleotide from the sample (page 4, paragraph 3) the target is detected by means of the labelled nucleic acid (page 5). Henson teaches that the order of reaction between the single stranded nucleic acid and the probe and the support may be varied according to experimental needs (page 6). It therefore would have been prima facie obvious to one of ordinary skill in the art at the time that the invention was made to modify the method of Vary by performing a separation/purification step prior to amplification given that techniques of capturing a target nucleic acid on a retrieveable solid support were routinely performed in the art to isolate a target sequence from a complex biological sample and given that such methods were known to provide the benefit of increased sensitivity and lower background in nucleic acid detection assays. One of ordinary skill in the art at the time that the invention was made would be well aware that enriching for a desired target sequence in a population of sequences prior to a PCR amplification step would provide a more sensitive assay for such reasons and have been motivated to do in view of the teachings of Vary to achieve the expected benefit of avoiding nonspecific signals that arise in PCR assays. The inclusion of reagents to be used in the method of Vary as

modified by Henson would have been further prima facie obvious to one of skill in the art at the time that the invention was made in view of the conventionality of kits in the analytical arts and their well known benefits of providing standardized reagents in a convenient form.

3. Claims 25-50 are rejected under 35 U.S.C. § 103 as being unpatentable over Vary et al. (USPAT 4851331,, filed May 16, 1986) in view of Henson et al. (ORTHO DIAGNOSTICS, EP 0 139 489, published 2/5/85) and further in view of Elazar Rabbani et al.(EP 0 159 719, published 10/30/85).

Vary in view of Henson et al. meet all of the limitations of the claims except for the teachings of a second support. However Rabbani et al. teaches a nucleic acid detection method which provides two probes as a means of detecting a single target wherein both probes may be labelled with particle and the particles may be macroparticles or microparticles (i.e retrieveable solid supports). Rabbani et al. teaches that an advantage to the method is to provide a highly sensitive, homogenous assay system. Thus it would have been prima facie obvious to one of ordinary skill in the art at the time that the invention was made to further modify the method as taught by Vary in view of Henson by using a probe labelled with a second support for the expected benefit of optimizing the sensitivity of the assay as taught by Rabbani et al.. It would have been further

prima facie obvious to one of ordinary skill in the art at the time that the invention was made to provide the compositions of Henson, Vary and Rabbani in a kit format, again for the expected benefit of provided for standardized reagents in a convenient format.

4.No claims are allowed.

5. The following references are cited as relevant intervening art:

Longiaru et al. (USPAT 5232829, filed Sept 29, 1989) teaches a method for amplifying a target polynucleotide in a sample comprising the steps of contacting the sample with a first support which binds a target polynucleotide (in this example the first support is the surface of a microtiter well to which is bound a capture oligonucleotide), substantially separating the support and bound target polynucleotide from the sample (washing the wells several times) . (see column 8).

Urdea (USPAT 5200314, filed March 23, 1990) teaches a method for amplifying and detecting a target polynucleotide by

contacting the target with a capture probe attached to a solid support (i.e the support binds to the target polynucleotide through the capture probe). The support and bound target polynucleotide is then separated from the sample . The target polynucleotide is then amplified by PCR with a polymerase and the amplified product is separated from the reaction mixture (see abstract). The support may further be a retrieveable support. (column 8) and the capture probe may be labelled (column 5).Urdea

Papers related to this application may be submitted to Group 1800 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center number is (703) 305-7401. Please note that the faxing of such papers must conform with the notice to Comply published in the Official Gazette, 1096 OG 30 (Nov 15, 1989).

An inquiry regarding this communication should be directed to examiner Dianne Rees, Ph.D., whose telephone number is (703) 308-6565. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1156.

Calls of a general nature may be directed to the Group receptionist who may be reached at (703) 308-0196.

W. GARY JONES
SUPERVISORY PATENT EXAMINER
GROUP 1800
6/19/96

Dianne Rees
Dianne Rees

June 18, 1996